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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,227	02/04/2004	Michelle L. Verbsky	12557-016001	2417

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,227	VERBSKY ET AL	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *22-27,29-37,39-53,62-72,75-78 and 82-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,54-60,86 and 88-93* is/are rejected.

7)☒ Claim(s) *21,28,38,61,73,74,79-81 and 87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 10/23/06 is acknowledged. The requirement is made Final.

Claims 1-93 are pending.

Claims 22-27, 29-37, 39-53, 62-72, 75-78, and 82-85 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1-21, 28, 38, 54-61, 73-74, 79-81, 86-93 are examined.

Specification

The disclosure is objected to because of the following informalities: for example page 20, line 15; page 21, line 29; page 28, line 4; page 56, lines 5, 10, 23, and 27, contain an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser-executable code is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 1, 21, 61, 74, and 87 are objected to for reciting the non-elected sequences. Correction is required.

Claims 2-3 recite "9^{th}" and "10^{th}" carbon positions, however, it is unclear where the counting of the carbon starts. Clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is indefinite because "the construct" of claim 1 lacks antecedent basis. Claim 1 is directed to a transgenic plant rather than a construct. Dependent claims 56-61 do not overcome the rejection, therefore are included in the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 54-60 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid of SEQ ID NO: 32, a transgenic plant comprising a nucleic acid encoding SEQ ID NO: 41 operably linked to a

vegetative-tissue specific promoter, and a method of producing said transgenic plant, does not reasonably provide enablement for a transgenic plant comprising a DNA encoding any polypeptide effective for catalyzing the conversion of a substrate to a C16, C18, or C20 monounsaturated fatty acid product having the structure as recited in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a transgenic plant containing at least one DNA construct comprising a nucleic acid encoding a polypeptide effective for catalyzing the conversion of a substrate to a C16, C18, or C20 monounsaturated fatty acid product having the structures as recited in claim 1, wherein the plant has increased amount of a hydroxyl fatty acids including ricinoleic or vernoleic in roots as compared to a plant that lacks said DNA. The Claims are also drawn to said plant further comprising a second DNA encoding PDAT or DAGAT polypeptide, and specified root-specific promoters.

The nucleic acid of the claims encodes a polypeptide of unknown function, and the function of the polypeptides cannot be predicted from its structure. The specification, however, states that the claimed transgenic plants would exhibit nematocidal activity as a result of expressing a nucleic acid encoding a polypeptide effective for catalyzing the conversion of a substrate to a C16, C18, or C20 monounsaturated fatty acid product having the structures as recited in claim 1. In contrast, the specification teaches transgenic plants expressing a DNA construct comprising SEQ ID NO: 32 in vegetative tissue having nematode resistance activity. The specification does not teach transgenic

plants comprising a DNA encoding any polypeptide effective for catalyzing the conversion of a substrate to a C16, C18, or C20 monounsaturated fatty acid product having the structure in claim 1, where X can be any of hydrogen, CoA, glycerol, a monoglyceride, a diglyceride, ACP, methyl, Na+, phosphatidylcholine, or phosphatidylethanolamine, wherein both R1 and R2 are hydroxyl, one of R1 and R2 is hydroxyl and the other is hydrogen, or one of RI and R2 is keto and the other is hydrogen, and wherein R3 is C2, C4, or C6 alkyl.

The prior art provides limited and inconsistent information regarding the nematocidal activity of fatty acids, let alone transgenic plants expressing fatty acids for nematocidal activity. For example, Djian et al. (1994) Pestic. Biochem. Physiol.50 (3): 229-239, Applicant's IDS) teach differential sensitivity of specific nematodes to various fatty acids. Djian et al show higher potent of nematocidal activity of shorter chain fatty acids against *Meloidogyne incognita* as compared to *Panagrellus redivivus.* Momin & Nair (2002) J. Agric. Food Chem. 50(16): 4475-4478, Applicant's IDS) show that high chain fatty acids such as oleic fatty acid at 100ug/ml is not nematicidal to either *Panagrellus redivivus* or *Caenorhabditis elegans*. While Stadler et al. (1994) Planta Medica 60(2): 128-132, Applicant's IDS) show that common longer chain of fatty acids such as oleic at 25ul/ml had significant nematicidal activity against C. elegans as compared to fatty acids with C6 to C10 chains.

The working examples provided in the specification are limited to invitro analysis of the nematocidal activity of SEQ ID NO: 32 (as the elected sequence). The specification provides no variant of SEQ ID NO: 32 or SEQ ID NO: 41 having

nematocidal activity upon expression in a transgenic plant. Therefore, the nematocodal activity of SEQ ID NO: 32 encoding SEQ ID NO: 41 cannot be extrapolated to polypeptides with the structures as recited in claim 1.

Therefore, when *In re Wands* factors (858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988) are considered, the claimed invention is not enabled throughout the broad scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 86 and 88-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (WO 98/46762, Applicant's IDS).

The claims are drawn to a transgenic plant comprising a nucleic acid encoding a fatty acid epoxygenase polypeptide or fatty acid hydroxylase polypeptide operably linked to a vegetative tissue specific regulatory element, the transformed plant having an increased amount of ricinoleic acid from 0.1% to about 0.25% or vernolic fatty acid from 0.1% to 0.35% of the total fatty acid in the root.

Green et al teach transformed plants comprising DNA sequences encoding plant fatty acid epoxygenase enzymes from Chrysanthemum spp., Crepis spp., Euphorbia spp., and methods of altering fatty acid composition and levels in plants. The cited reference also teaches a method of altering the level of epoxy fatty acids in a plant cell, tissue or organ by transforming the plant with a nucleic acid encoding fatty acid epoxygenase under the control of CaMV 35S promoter, and transgenic plants with increased levels of vernolic acid (12, 13-epoxy-9-octadecenoic acid) as compared to non-transformed plants (see Examples 5-11 and claims 45-49). While Green et al do not expressly teach transgenic plants with levels of 0.1% to 25% or 35% of the plant epoxygenase/hydroxylase, since CaMV 35S promoter provides strong constitutive gene expressions, one would expect increased expression of the epoxygenase/hydroxylase at levels of 0.1% to 35% in both vegetative and non-vegetative tissues of the transformed plant.

Remarks

SEQ ID NO: 32 and nucleic acid encoding SEQ ID NO: 41 are free of the prior art.

Claims 21, 28, 38, 61, 73-74, 79-81, and 87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12/21/06
Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER